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(Original Signature of Member)

115TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To amend the Controlled Substances Act to deem drugs or other substances that act as opioid mu receptor agonists to be in schedule I, subject to exceptions for substances intended for legitimate medical or research use, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. ROE of Tennessee introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend the Controlled Substances Act to deem drugs or other substances that act as opioid mu receptor agonists to be in schedule I, subject to exceptions for substances intended for legitimate medical or research use, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Modernizing Drug En-  
5 forcement Act of 2018”.

1 **SEC. 2. DRUGS OR OTHER SUBSTANCES THAT ACT AS**  
2 **OPIOID MU RECEPTOR AGONISTS.**

3 (a) DEFINITIONS.—Paragraph (18) of section 102 of  
4 the Controlled Substances Act (21 U.S.C. 802) is amend-  
5 ed to read as follows:

6 “(18)(A) The term ‘opiate’ or ‘opioid’—

7 “(i) means any drug or other substance having  
8 an addiction-forming or addiction-sustaining liability  
9 similar to morphine or being capable of conversion  
10 into a drug having such addiction-forming or addic-  
11 tion-sustaining liability; and

12 “(ii) includes any drug or other substance that  
13 acts as an opioid mu receptor agonist.

14 “(B) The term ‘opioid mu receptor’ is a molecule that  
15 when bound to, and activated by, an opioid mu receptor  
16 agonist would result in analgesia, euphoria, addiction, or  
17 respiratory depression in the central nervous system.

18 “(C) The term ‘opioid mu receptor agonist’ is a sub-  
19 stance that when bound to, and interacting with, the  
20 opioid mu receptor, activates the receptor to result in anal-  
21 gesia, euphoria, addiction, or respiratory depression.”.

22 (b) SCHEDULING.—Section 201 of the Controlled  
23 Substances Act (21 U.S.C. 811) is amended by adding at  
24 the end the following:

25 “(k) OPIOID MU RECEPTOR AGONISTS.—

1           “(1) IN GENERAL.—Effective as of the date of  
2           enactment of the Modernizing Drug Enforcement  
3           Act of 2018, schedule I under section 202 is deemed  
4           to include, unless specifically exempted or unless  
5           listed in another schedule, any chemical substances,  
6           including their salts, isomers, and salts of isomers  
7           whenever the existence of such salts, isomers, and  
8           salts of isomers is possible, that act as opioid mu re-  
9           ceptor agonists, and any material, compound, mix-  
10          ture, or preparation that contains any quantity of  
11          such substances.

12           “(2) EXCEPTIONS.—A chemical substance is ex-  
13          empt from inclusion in schedule I by operation of  
14          paragraph (1) if the substance—

15                   “(A) is the subject of an approved applica-  
16                   tion submitted under subsection (b) or (j) of  
17                   section 505 of the Federal Food, Drug, and  
18                   Cosmetic Act;

19                   “(B) is exempt from the provisions of sec-  
20                   tion 505 of such Act relating to new drugs be-  
21                   cause—

22                           “(i) the substance is intended solely  
23                           for investigational use as described in sec-  
24                           tion 505(i) of such Act; and

1           “(ii) the substance is being used ex-  
2           clusively for purposes of a clinical trial  
3           that is the subject of an effective investiga-  
4           tional new drug application; or

5           “(C) is the subject of a nonclinical drug in-  
6           vestigation by experts qualified by scientific  
7           training and experience to investigate the safety  
8           and effectiveness of drugs.

9           “(3) LISTING.—Not later than 180 days after  
10          the date of enactment of the Modernizing Drug En-  
11          forcement Act of 2018, the Attorney General shall  
12          update schedule I in accordance with paragraph (1).  
13          The Attorney General may list substances in sched-  
14          ule I pursuant to paragraph (1) without regard to  
15          the process and considerations that are otherwise  
16          applicable under this section for adding, removing,  
17          or transferring controlled substances to, from, or  
18          among the schedules under section 202.”.